AUG 1 0 2001

K012385

GE Medical Systems

General Electric Company
PO Box 414, Milwaukee, WI 53201

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of Safety and Effectiveness information is submitted in accordance with the requirement of 21 CFR Part 807.87(h).

Submitter: Larry A. Kroger, Ph.D.
Senior Regulatory Programs Manager
TEL: 262-544-3894, FAX: 262-544-3863
Summary prepared: June 22, 2001

PRODUCT IDENTIFICATION

Name: HiSpeed X/i Smart Gantry Option

Classification Name: Computed Tomography X-ray System

Manufacturer: General Electric YMS
7-127 Asahigaoka 4-Chome
Hino-Shi, Tokyo, Japan 191

Distributor: General Electric Medical Systems
3000 N. Grandview Blvd.
Waukesha, WI 53188

Marketed Devices: The HiSpeed X/i Smart Gantry Option CT Scanner System is of comparable type and substantially equivalent to currently marketed Computed Tomography X-ray Systems that comply with the same or equivalent standards and have the same intended uses.

DEVICE DESCRIPTION

The HiSpeed X/i Smart Gantry Option CT Scanner System is composed of a gantry, shared patient table, console, computer, and associated accessories.

Materials: Materials and construction are equivalent to the HiSpeed Family of CT Systems (K980169) are compliant with UL 2601, IEC 60061-1, and 21CFR Subchapter J.

Design: The system is designed to be a head and whole body CT scanner utilizing a solid state detector, an intuitive Operator Console, and the same tube and similar features to the HiSpeed Family of CT Systems (K980169), but now the gantry is on a dolly that travels on rails to provide

the capability of scanning by gantry travel instead of cradle travel. The stationary table/cradle to be used is a table that will be shared with a Linear Accelerator. The table/cradle will remain stationary while CT scanning is in progress. No claims related to the table's use outside of CT scanning are being made in this 510(k).

Indications for Use:

The HiSpeed X/i Smart Gantry Option CT Scanner System is indicated for head and whole body X-ray Computed Tomography applications.

Comparison with Predicate:

It is the opinion of GE Medical Systems that the HiSpeed X/i Smart Gantry Option CT Scanner System is of a type and substantially equivalent to currently marketed head and whole body X-ray computed topography systems with respect to design, material composition, energy source, and radiation characteristics. It will comply with the X-ray requirements of 21CFR1020.30, 1020.31, and1020.33, as well as the safety requirements of UL2601, IEC 60601 and collateral standards.

Adverse Effects on Health:

Potential electrical, mechanical and radiation hazards are identified in a risk management summary (hazard analysis) and controlled by:

- System verification and validation to ensure performance to specifications, Federal Regulations, and user requirements.
- Adherence to industry and international standards. (UL/CSA and IEC).

CONCLUSIONS

The HiSpeed X/i Smart Gantry Option CT Scanner System does not result in any new potential safety risks and performs as well as or better than devices currently on the market. GE considers the HiSpeed X/i Smart Gantry Option CT Scanner System to be equivalent to other marketed devices with the same indications for use and meeting similar standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 0 2001

GE Medical Systems, Inc.
Mr. Reiner Krumme
TUV Rheinland of North America
12 Commerce Road
NEWTOWN CT 06470

Re: K012385
HiSpeed X/i Smart Gantry Option
Dated: July 24, 2001
Received: July 27, 2001
Regulatory Class: II
21 CFR 892.1750/Procode: 90 JAK

Dear Mr. Krumme:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

STATEMENT OF INTENDED USE

510(k) Number (if known): K012385

Device Name: HiSpeed X/i Smart Gantry Option CT Scanner System

Indications For Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ -OR- Over-The-Counter Use _____
(Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K012385